MQSA PROGRAM ACCOMPLISHMENTS

June 1993 Through May 2000

FDA's Division of Mammography Quality and Radiation Programs

After Congress passed the Mammography Quality Standards Act of 1992 (MQSA), the Food and Drug Administration (FDA) received authority from the Department of Health and Human Services to implement MQSA. As a result, the Division of Mammography Quality and Radiation Programs (DMQRP) was established in FDA's Center for Devices and Radiological Health.

(Besides implementing MQSA, the division also directs other radiation program activities.)

On October 9, 1998, the Mammography Quality Standards Reauthorization Act of 1998 (MQSRA) was enacted, extending the program to 2002.

Key Milestones

- MQSA enacted – October 1992
- FDA delegated responsibility – June 1993
- Interim regulations issued – December 1993
- Interim regulations effective – February 1994
- First accreditation body approved – March 1994
- All mammography facilities certified – October 1994
- Annual inspections begun – January 1995
- Final regulations issued – October 1997
- States-As-Certifiers (SAC) pilot initiated – August 1998
- MQSRA enacted – October 1998
- Final regulations effective – April 1999
- SAC proposed regulations published for comment – March 2000
- Screen/film facility certification can be extended to include Full Field Digital Mammography (FFDM) – March 2000

The Program Director

The Director of the division is John McCrohan, M.S., a Captain in the Public Health Service. Before this appointment, he served as the Division's Deputy Director and was previously involved with mammography through the "Breast Exposure: Nationwide Trends (BENT)" and the "Nationwide Evaluation of X-ray Trends (NEXT)" programs.

Standards Development

On December 21, 1993, FDA published interim regulations for mammography facilities and accreditation bodies, effective February 22, 1994. Development of the final regulations began with the first meeting of the National Mammography Quality Assurance Advisory Committee in February 1994. Proposed rules were published on April 3, 1996, with a 90-day comment period. FDA analyzed over 1,900 letters and considered approximately 8,000 comments during this development process. On October 28, 1997, FDA issued the more comprehensive final regulations that became effective on April 28, 1999.

Since 1994, FDA has issued guidance documents designed to help facilities comply with the regulations. These have been incorporated into the Policy Guidance Help System (a computerized search engine) that is available on our web site at www.fda.gov/cdrh/mammography. FDA continues to update its guidance in response to facility and consumer inquiries.

Accreditation Bodies

FDA has approved five accreditation bodies under MQSA: the American College of Radiology (ACR), the State of California, the State of Arkansas, the State of Iowa, and the State of Texas. The agency reports annually to Congress about the performance of these accreditation bodies.

Facility Certification

As of April 28, 2000, there were 9,994 MQSA-certified mammography facilities in the U.S. and its territories. Of these, 9,570 facilities are fully certified. The remainder are provisionally certified, while in the process of becoming accredited. Facilities that fail accreditation must cease providing mammography services. However, once the deficiencies resulting in failure are corrected, a facility may apply for reinstatement to resume the accreditation process. Facility certification can now be extended to include FDA-approved digital mammography units. To track certification activities and other aspects of the MQSA program, FDA uses state-of-the-art information technology, the Mammography Program Reporting and Information System (MPRIS), which allows FDA to access MQSA compliance.

States as Certifiers (SAC)

In June 1996, FDA established a States as Certifiers (SAC) Working Group to assist in developing procedures and regulations for the transfer of certification authority from FDA to applicant States, as provided for by MQSA. In August 1998, FDA implemented a SAC Demonstration Project with the States of Iowa and Illinois. The demonstration project will run for approximately 3 years. Proposed

regulations to implement the program on a nationwide basis were published on March 30, 2000, with a 90-day comment period. Final regulations are projected to go into effect around April 2001. Responsibilities delegated to the participating States include:

- Issuance, renewal, suspension, and revocation of certificates for mammography facilities within the State;
- annual facility inspections;
- all compliance actions for any findings upon inspection.

Inspections and Inspector Training

Under MQSA, trained inspectors with the Food and Drug Administration, with State agencies under contract to the FDA, and with States that are certifying agencies, perform annual MQSA inspections. Only FDA can perform annual inspections of federal facilities. As of September 20, 1999, forty-six States and three jurisdictions have contracts. Since the inception of the MQSA inspection program in 1995, more than 40,000 facility inspections have been conducted.

As part of MQSRA, a demonstration program for conducting less frequent inspections of facilities with excellent inspection records is projected to begin after April 1, 2001.

MQSA inspectors must be certified according to qualifications established by FDA and maintain their certification based on requirements that are similar to those for facility personnel. The agency's program emphasizes hands-on training that consists of three, two-week courses. Since 1994, FDA has trained a total of 344 inspectors. Currently there are 236 active certified inspectors. Of those, 206 are State inspectors and the remaining 30 are FDA inspectors. In addition, FDA has an Inspector Quality Assurance Program to assist inspectors throughout their tenure.

State-of-the-Art Equipment Used During Inspections

Inspectors perform science-based inspections to determine the radiation dose for the standard breast, to assess image quality using a standard image quality phantom, and to empirically evaluate the quality of the facility's film processing. In addition, inspectors review the facility's medical reports, lay summaries and medical audit to assure that the facility's procedures meet the requirements. The facility's quality assurance and quality control records are also reviewed. In addition, each facility's darkroom is tested for unsafe ambient light levels that may adversely affect image quality. The testing equipment used during inspections is calibrated annually by FDA in a state-of-the-art laboratory to ensure the accuracy of measurements and inspections. In addition, inspections are conducted using laptop computers that can be connected to the FDA MPRIS database.

Inspection Fees

MQSA requires FDA to collect fees from facilities to cover the cost of their annual facility inspections. Effective February 13, 1998, the fee is $1,549 for the first mammography unit and $204 for each additional unit. The fee for a follow-up inspection, if needed to assure that problems found on the first inspection have been corrected, is $878.

MQSA exempts "government entities" from fees. Government entities include any facility operated by a State, territory, possession, city, county, town, village, municipality, or federally recognized Native American tribe. In addition, facilities that have at least 50% of their screening mammograms funded under the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Title XV of the Public Health Service Act) are considered government entities under MQSA. The costs of inspecting government entities are paid through federal funding appropriated to FDA, not by other facilities.

Compliance and Enforcement

FDA has a compliance and enforcement program to help ensure quality mammography. To this end, mammography facilities are inspected annually using a three level system for inspection findings:

- A ***Level 1*** finding is issued when the agency has found deviations from the MQSA standards that may seriously compromise the quality of mammography services offered by a facility. In such cases, facilities will usually be sent a Warning Letter from FDA to which they must respond in writing within 15 days.

- A ***Level 2*** finding is issued when FDA has found deviations from the MQSA standards that may compromise the quality of mammography services offered by a facility, but the deviations are not as serious as those for Level 1. In these cases, facilities are required to respond in writing within 30 days following their inspection.

- A ***Level 3*** finding is issued when a facility was satisfactory, in general, but where some minor deviations from the MQSA standards were found. These facilities are not required to respond in writing to FDA, but the agency checks on the correction of these findings during the next annual facility inspection.

The table below summarizes FDA's inspection results over the course of the program:

Fiscal Year*	# Facilities	No Findings	Level 1	Level 2	Level 3
1995	4851	30.0%	2.6%	19.9%	47.6%
1996	8803	42.7%	1.6%	12.5%	42.3%
1997	9448	55.9%	0.9%	12.5%	30.7%
1998	9297	58.2%	1.1%	18.9%	21.9%
1999	9537	58.4%	1.7%	23.5%	16.2%
2000**	3771	50.6%	4.8%	34.0%	10.5%

*FDA fiscal year, starting on October 1st and ending on September 30th.
** Fiscal Year 2000, as of March 6, 2000

You may notice that the number of Level 1 and Level 2 findings for Fiscal Year 2000 have increased. We believe that the increase is the result of some facilities not being familiar with some requirements of the final regulations. In addition, under the final regulations some Level 2 findings were elevated to Level 1 findings and some Level 3 findings were elevated to Level 2 findings. We expect these numbers to decline when facilities get their second annual inspection under the final regulations.

When necessary, FDA may use MQSA sanctions including: 1) Directed Plan of Corrections; 2) Civil Money Penalties; 3) suspension of facility certificates; 4) revocation of facility certificates; and 5) injunctions.

Since 1995, there have been three criminal convictions involving fraud at mammography facilities. In each case, the criminal activity was related to falsification of records.

Sometimes FDA may require a facility to notify its patients and their referring healthcare providers about problems at that facility that may have an effect on the quality of their mammograms.

Outreach Activities

Approaches that FDA uses to inform mammography facilities and the public about MQSA requirements include the following:

- a Facility Hotline for responding to questions from facility staff (phone 1-800-838-7715);
- a web site on the FDA Internet @ http://www.fda.gov/cdrh/mammography, with facility guidance

issued by FDA including a policy search engine;
- a quarterly newsletter, *Mammography Matters*, for facilities and other interested parties. Published since Winter 1994, and now available electronically on the mammography web site;
- a brochure for patients, *Mammography Today*, that clarifies patients' rights resulting from MQSA;
- a live, inter-active teleconference to all MQSA facilities was broadcast on February 18, 1999, focusing on the final regulations;
- a consumer brochure, *Things to Know About Quality Mammograms* (published in cooperation with the Agency for Health Care Policy and Research);
- a brochure, *MQSA and You*, *Making Quality a Reality*, A Resource Guide for Facilities, Health Professionals, Inspectors, and the Public; and
- collaboration with NIH to provide a list of MQSA-certified facilities available on the web site or by phoning 1-800-4-CANCER.

Program Evaluation

According to the General Accounting Office's October 1997 report on the mammography program, MQSA has a positive impact on mammography quality. Inspection data continues to show facilities increasing compliance with the national standards and in the quality of x-ray images. In 1992, prior to MQSA, only 89% of the mammography facilities that chose voluntary accreditation passed the phantom image test on their first try even though in general it was these facilities that were among the best facilities practicing mammography. Currently, 98% of all mammography facilities pass the phantom image test during their facility inspection. Experts agree that improving the quality of images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer. Through inspections and data from accreditation bodies, FDA monitors MQSA's impact on mammography quality, including radiation exposure levels.

More information about the impact of MQSA is contained in the following GAO reports:

- October 1995 – "Mammography Services: Initial Impact of New Federal Law Has Been Positive."

- January 1997 – "FDA's Mammography Inspections: While Some Problems Need Attention, Facility Compliance is Growing."

- October 1997 – "Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes."

In April 1997, FDA surveyed facilities to determine the level of satisfaction with inspections. An analysis of the results mailed to facilities in July of 1998 showed general satisfaction with the inspection process and inspector conduct.

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